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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/762,769 | 01/21/2004 | Anastasios Melis | BERK-016CIP | 3105 |

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/762,769 | | MELIS ET AL. | |
| | Examiner | | Art Unit | |
| | Ganapathirama Raghu | | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-31 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to a method of hydrogen gas generation comprising the steps of culturing unicellular, photosynthetic, anoxygenic algae under illuminated conditions in sulfur containing media, wherein the sulfate permease expression of algae is reduced compared to the wild-type, classified in class 435, subclass 41.
- II. Claim 10, drawn to isolated polynucleotide with SEQ ID NOs: 2, 3, 4, 5, and 6, and a sequence which hybridizes to any one of the said sequences, classified in class 536, subclass 23.1.
- III. Claim 11, drawn to an isolated polypeptide with SEQ ID NO: 1, classified in class 435, subclass 183+.
- IV. Claims 12-18, drawn to a product, genetically modified algae wherein the sulfate uptake pathway is downregulated 50% or less relative to wild-type, wherein expression of endogenous gene *CrcpSulP* is downregulated by insertion of antisense sequence to the said gene mRNA transcript, classified in class 435, subclass 257.1.
- V. Claim 19, drawn to an assay for detecting low levels of sulfur uptake and aryl-sulfatase activity, classified in class 435, subclass 6.

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- VI. Claims 20-22, drawn to an isolated antisense oligonucleotide, consisting of a sequence complementary to SEQ ID NO: 2 and an expression vector, classified in class 435, subclass 320.1.
- VII. Claims 23-24, drawn to a composition comprising of algae and bacteria, classified in class 435, subclass 252.1+.
- VIII. Claims 25-31, drawn to a method of generating hydrogen gas comprising the use of algae, photosynthetic bacteria and Clostridium, classified in class 435, subclass 42.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions II, III, IV, VI, VII are all products and patentably distinct from each other. The polynucleotide of group II and the antisense oligonucleotide of group VI are composed of purines and pyrimidines, polypeptide of group III are composed of amino acids, the algae and growth media for group of IV and VII are all structurally and functionally different from each other, do not require each other for practice; have separate utilities. For example, the use of polynucleotide in group II as a hybridization probe versus polypeptide of group III to catalyze a reaction are subject to separate manufacture and sale.

Inventions I, V, VIII are methods or processes and patentably distinct from each other. Each of the processes has different steps, using different components and modes of operation with different end results. They do not require each other for practice; have separate utilities. For

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example, the method of hydrogen gas generation in group I and group VIII, the method of detecting sulfur uptake by aryl-sulfatase activity in group V, require different kinds of preparation and mode of use, and are subject to separate manufacture and sale.

Inventions II, VI and I, V, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the polynucleotide of group II and the antisense oligonucleotide of group VII are neither used nor made in the method of groups I and VIII, that require the use of algae, bacteria to generate hydrogen gas or group V for the detection of enzyme activity, and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention III and V, are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of group III can be used as an antigen to raise specific antibodies as opposed to its use to in group V as an enzyme to catalyze a reaction in detection assay.

Invention III and I, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the polypeptide of group III is neither used nor made in the method of

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groups I and VIII, that require the use of algae, bacteria to generate hydrogen gas and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention IV and I, V, VIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the algae of group IV can be used as a source for making macromolecules like DNA, polypeptides and intermediate metabolic products as opposed to its use to in groups I and VIII for the production of hydrogen gas or group V to determine the sulfur uptake by aryl-sulfatase enzyme assay gas and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention VII and I, V, VIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the mixture of algae and bacteria of group VII can be used as a source for making macromolecules like DNA, polypeptides and intermediate metabolic products as opposed to its use to in groups I and VIII for the production of hydrogen gas or group V to determine the sulfur uptake by aryl-sulfatase enzyme assay gas and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Election of Sequence

Group II contains claim directed to the following patentably distinct species of the claimed invention: the various polynucleotide sequences with SEQ ID NOS: 2, 3, 4, 5, and 6. Furthermore these sequences have different structure.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single appropriate disclosed species i.e., a single SEQ ID NO: associated with the respective group for prosecution on the merits to which the claims are restricted. Note that this is a restriction requirement to sequence and NOT a species election.

MPEP 803.04 states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141et seq. It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Examination will be restricted to only the elected group and the elected amino acid /nucleotide sequence.

Hence, the above inventions have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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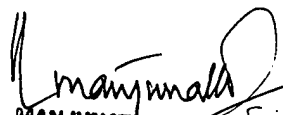
patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

November 17, 2005


MANJUNATH N. RAO, Ph.D.
PRIMARY EXAMINER